

Included in the American
Cancer Society 2003 Colorectal
Cancer Screening Guidelines Update!

**For ease and convenience
in colorectal cancer screening...**

Saved by the Brush



Fecal Immunochemical Test

Simple. Sensitive. Specific.

The difference is clear

	InSure™ Fecal Immunochemical Test	Hemoccult II® SENSE®
Dietary and medicinal restrictions	None² InSure FIT is specific for the globin portion of human hemoglobin and does not react with non-human vitamins, drugs, or peroxidase from food sources	Yes^{3,5,6} Restricted drugs and foods include non-steroidal anti-inflammatory drugs, vitamin C, fruit juices, and red meats, among others
Fecal handling	No² A long-handled brush is used to brush the surface of the stool in the toilet bowl	Yes³
Number of samples needed	2²	6³ (Two samples collected on three different days)
Screens entire colon	Yes	Yes
Invasive	No	No
Frequency	Annual	Annual
CPT code*	82274	82270
IN AN ONGOING STUDY OF INSURE FIT VS. HEMOCCULT II SENSE^{***}:		
Sensitivity for colorectal cancer	88.9%	50%
Sensitivity for significant neoplasia	77.1%	42.9%



“ In comparison with guaiac-based tests for the detection of occult blood, immunochemical tests are more patient-friendly, and are likely to be equal or better in sensitivity and specificity. ”

American Cancer Society guidelines for the early detection of cancer¹

* The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor billed.

** This study is ongoing in Australia and compares InForm® to Hemoccult II SENSE. InForm is the brand name for InSure FIT in Australia. InForm is identical in all respects to InSure FIT, including directions for use.

The proof is in the numbers



87%
Sensitivity for
colorectal cancer

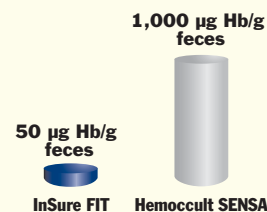
In a clinical trial of 240 people, InSure™ FIT was shown to have 87% sensitivity for cancer.²

98%
Specificity for
significant neoplasia

InSure FIT provides accurate screening with less worry about false positives.²

**InSure FIT detects blood
with greater sensitivity**

In Vitro Sensitivity^{2,3*}



*Amount of Hb/g of feces needed to achieve 100% sensitivity

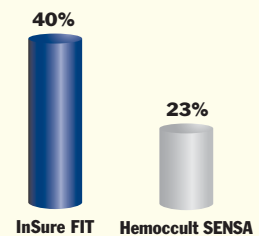
The test more patients use

66% More patient compliance

InSure FIT may allow up to 66% more patient compliance than Hemocult® SENSEA®⁴

- Simple, patient-friendly sampling
- Long-handled brush allows for no fecal handling
- No dietary or medicinal restrictions
- Easy brush process with only two samples required

Improved patient compliance with InSure FIT⁴



Participation rate
at 12 weeks



Easy and convenient

For you And your patients



The physician enters the diagnosis code, signs the reply form and gives the kit to the patient.



STEP 1

The patient flushes the toilet before a bowel movement.



STEP 2

After each of two successive bowel movements, toilet paper is placed in a waste bag provided.



STEP 3

The patient lifts the flap on the InSure test card marked "Lift here for sample 1." (Process is repeated for sample 2 after next bowel movement.)



STEP 4

Using one of the patented long-handled brushes, the patient gently brushes the surface of the stool for about 5 seconds.



STEP 5

The patient touches the test card with the tip of the brush for about 5 seconds.



STEP 6

One of the two removable labels from the Reply Form is used to reveal the flap marked "Sample 1," and the patient prints his or her name on the label.



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The patient mails the card in the postage-paid envelope.

It is processed at the local Quest Diagnostics facility, which then sends the test results to the physician.

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In colorectal
cancer screening...

Simple Sensitive Specific



Only InSure FIT provides:

- Patient-friendly sampling with no fecal handling and no dietary or medicinal restrictions
- 87% sensitivity for colorectal cancer²
- 98% specificity for significant neoplasia²
- Up to 66% more patient compliance than guaiac-based fecal occult blood tests⁴

InSure FIT is specific for the globin portion of human hemoglobin.²

Laboratory services provided
through Quest Diagnostics



Quest
Diagnostics®



References: 1. Smith RA, Cokkinides V, Eyre HJ. American Cancer Society guidelines for the early detection of cancer, 2003. *CA Cancer J Clin.* 2003;53:27-43. 2. Enterix Inc., data on file. 3. Hemocult® SENA® Patient Instructions. Available at: <http://www.hemocultfobt.com/p/p.asp?mlid=64>. Accessed September 10, 2003. 4. Cole SR, Young FP, Esterman A, et al. A randomised trial of the impact of new faecal haemoglobin test technologies on population participation in screening for colorectal cancer. *J Med Screen.* 2003;10:117-122. 5. Levin B, Brooks D, Smith RA, et al. Emerging technologies in screening for colorectal cancer: CT colonography, immunochemical fecal occult blood tests, and stool screening using molecular markers. *CA Cancer J Clin.* 2003;53:44-55. 6. Allison JE, Tekawa IS, Ransom LJ, et al. A comparison of fecal occult-blood tests for colorectal-cancer screening. *N Engl J Med.* 1996;334:155-159. 7. Cole SR, Smith A, Bampton P, et al. Colorectal cancer screening: direct comparison of a brush-sampling faecal immunochemical test for haemoglobin with a guaiac FOBT. Paper presented at: Australian Gastro Week; 2003; Cairns, Australia.

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